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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,767	05/14/2001	Isao Horiuchi	HORIUCHI-6	9992

1444 7590 05/07/2003  
BROWDY AND NEIMARK, P.L.L.C.  
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SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/831,767

Applicant(s)

HORIUCHI, ISAO

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Claims 9-12 are pending. The Amendment filed 3/17/03, Paper No. 7, cancelled claims 1-8.

Applicant's amendment, which cancelled all of the previous pending claims, is persuasive to overcome the 35 USC 112, 102, and 103 rejections in the previous Office Action.

Applicant's arguments with respect to claims 9-11 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the instant rejection, the Examiner will address them.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru et al. (05-017363) and JP 11199429.

Minoru et al. teach cosmetic compositions comprising 0.01-10% of bacterial cells of the genus *Lactobacillus* as the active ingredient. The bacterial cells are obtained by culturing, collecting and washing of lactic acid according to ordinary methods. The compositions are effective in treating skin inflammation. See abstract. The reference does not teach a protease.

JP '429 teaches anti-inflammatory cosmetic compositions comprising a mixture of alkali hydroxide solution and a culture filtrate of *Agaricus blazei* Murill extract. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the composition of Minoru et al. and JP '429 because a) it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose (In re Kerkoven, 205 USPQ 1069 (CCPA 1980)); and b) because of the expectation of achieving enhanced anti-inflammatory effects.

Though JP '429 does not teach the percent amount of the *Agaricus blazei* extract, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the limitations of claim 11, the Examiner respectfully points out that a compound and its properties are inseparable (In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Thus, since Minoru et al. teach culture supernatant of lactic acid bacteria, the composition of Minoru et al. must have the property recited in claim 11.

### ***Response to Arguments***

Applicants argue that their invention is unobvious over JP '429 because they have achieved unexpected results. Applicants have directed the Examiner to page 25 of the specification and to tables 7-12. Page 25 and tables 7-12 of the instant specification are not persuasive to show unexpected results. The Examiner respectfully directs Applicants to guidelines for showing unexpected results.

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated

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with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

Regarding the Examiner's 112, 1<sup>st</sup> paragraph, Applicants argue, "The PTO seems to take the position that much of what applicant originally claimed would have been unobvious, even with applicant's specification as guidance". This argument is not persuasive, as it appears that the Examiner's 35 USC 112, 1<sup>st</sup> paragraph, rejection has been misconstrued. It is respectfully pointed out that the PTO took the position that the previous claims were not enabled for any proteases and not that the claims were unobvious.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
April 25, 2003



SREENI PADMANABHAN  
PRIMARY EXAMINER

5/4/03